was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 4 and 19 were rejected under 35 U.S.C. 112 first paragraph as having a limitation that the Examiner maintains was not disclosed/described in the specification. Claims 1-6,10-13,15,16,19-22,25-30,46, and 47 were rejected under 35 U.S.C. 112 second paragraph "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention". Claims 36-41 were rejected under 35 U.S.C. 102(b) "as being clearly anticipated by Camilli" (US 5,607,465). Claims 1-5,10-12, and 36-41 were rejected under 35 U.S.C. 102(b) "as being clearly anticipated by Cox" (US 5,713,950). Claims 1-5, 12, 15, 16, 19-22, 25, 28, "27", "28", 29, 36-41, and 46. Claims 1,3-10,12-19, and 21 were rejected under 35 U.S.C. 103(a) "as being unpatentable over Harley et al. (WO 99/29262) in view of Avellanet (US 6,036,725)". By this response, Applicants cancel claims 37-41, renumber two claims as claims 48 and 49, and add new claims 50-55.

Claim Objections

Examiner's Point No. 3

The second set of claims 27 and 28, which are different than the first set, are renumbered as claims 48 and 49.

Claim Rejections - 35 USC §112

Examiner's Point No. 5:

Applicants maintain that 35 U.S.C. 112, first paragraph only requires that the best mode contemplated by the inventors be disclosed within the application. There is no requirement that claims include all of the elements of the best mode. It is assumed that the lack of the support structure or frame in the claims is what the Examiner finds objectionable. The support structure is clearly included in the drawings

and specification, thus satisfying the statute. Nevertheless, Applicants are amending claim 1 to include support structure or frame language that obviates this rejection. In no way should this action be interpreted that Applicants concede that they are not in compliance with 35 U.S.C. 112, first paragraph with regard to any claim. Applicants wish to emphasize that within the specification, they have characterized the term 'frame' to include both separate and integral structure, made from a variety of materials, including the frame being formed from the same material as the leaflet (page 18, lines 8-22).

Examiner's Point No. 6a:

Page 23, line 18 of the specification includes the phrase, 'overhang 80 of material', thus providing adequate support for the term 'overhanging material' in claim 4. This claim limitation is well illustrated in FIGs. 26-27. Therefore, Applicants disagree with the Examiner's rejection of claim 4 on this basis.

Examiner's Point No. 6b:

In regard to Examiner's point that the specification does not disclose/describe 'one or more flexible materials', Applicants wish to point to two places in the specification for support. On page 18, lines 18-22, it is stated that the leaflets can comprise multilaminate constructs. Since such constructs may include both synthetic and naturally-occurring materials, as stated, one skilled in the art would reasonably conclude that a multilaminate valve leaflet could comprise a combination of these materials. On page 24, lines 15-19, it is disclosed that the covering could include a thin coating or layer of material to improve its function. Such a layer would constitute at least a second material and obviously, would be flexible. Thus, Applicants argue that the term 'one or more flexible materials' is supported by the specification.

Examiner's Point No. 8a:

Claim 1 has been amended to include the word 'one' after 'or another' and 'of each' to make the claim language more explicit in that regard. As for Examiner's objection to the limitation 'at least substantially occlude fluid flow', those skilled in the art would recognize that a valve designed for the venous system would experience at least a small amount of leakage while nevertheless serving as a valve, improving net flow in a given direction in the vascular environment as long as the column of blood is largely prevented from passing back through, the valve can function beneficially. An incompetent native valve is not one having a small amount of leakage. Rather, an incompetent valve generally prevents little of the blood from refluxing back through the leaflets, thus causing swelling in the lower legs and feet as the pooling blood is largely unable to be pumped back toward the heart. A certain amount of minor leakage will not compromise the success of the valve. Nevertheless, the offending language is amended from 'at least substantially occlude' to 'restrict', since the later term also describes impeding or stopping reverse flow in a manner improving overall blood flow.

Examiner's Point No. 8b-c:

Both problems with the missing antecedent is corrected in Claim 2.

Examiner's Point No. 8d:

Claim 5 has been amended and the offending language is removed.

Examiner's Points No. 8e-f:

Claims 6 and 10 are amended to remove the term 'the covering', thus no antecedent is needed in claim 1.

Examiner's Point No. 8g:

Claim 11 has been amended so that is correctly depends from claim 10, which includes the missing antecedent.

Examiner's Point No. 8h:

Claim 19 has been amended to include the missing antecedent.

Examiner's Point No. 8i:

The objection to 'generally flat' also arose during prosecution of the parent case (U.S. 6,200,336) and the Applicants successfully argued that because of the nature of a resilient frame made of malleable wire and having corner bends in which the wire crosses itself, it is impossible for the frame to lie within a single flat plane. Strictly speaking, a geometric plane has a infinitesimally small width. No frame formed by bending wire can be made to lie within a single plane in the strict sense. The term 'generally flat' would be understood by one skilled in the art as it is applied to this particular embodiment of the present invention and such language would readily distinguish the claimed embodiment over other embodiments of artificial valves in which the frame is usually formed in a tubular configuration (as are some other embodiments in the present invention), or at the very least, not at all flat in any of the configurations the frame can assume. Applicant's use of the term 'generally' is needed to account for the inevitable deformation of the frame inherent in this particular embodiment. The Examiner in that case agreed with our arguments and Claim 1 in the parent case was allowed, reading as follows:

1. A multiple-sided intraluminal medical device comprising:
a single frame (11) having a closed circumference (62) with an aperture (56) therethrough, said closed circumference

having a plurality of sides (13), adjacent sides of said plurality of sides being interconnected by at least one bend (12), said frame adapted to assume a plurality of configurations, a first configuration (35) of said plurality of configurations being in a generally flat plane.

Thus, for the same reasons as we have argued before, 'generally flat' does not render the claim indefinite and thus, claim 29 should be allowed.

Examiner's Point No. 8j:

Claim 46 is being amended in a similar manner to claim 1 to replace 'or another' with 'leaflet'. The term 'at least substantially occlude' has been replaced with 'restrict' as explained above, thereby obviating the Examiner's objection.

Examiner's Point No. 8k:

Applicants are amending claim 47 to add the missing antecedent for 'the second end'. Again the term 'at least substantially reduce' has been replaced with 'restrict', making the objection moot.

Claim Rejections - 35 USC §102

Examiner's Point No. 10:

In each of claims 36-41, the covering includes an orifice extending therethrough. The Camilli covering (2) is a 'monocusp sail-like valve element' that lacks any opening through the material itself. In contrast, the covering in claims 36-41 includes an orifice or opening being formed within the perimeter of the covering such that the covering defines the borders thereof when in the open position. As disclosed in page 21, lines 10-14, this is done by either making a slit in the covering after it is attached to the frame to form a series of leaflets, or by

attaching multiple leaflets to the frame in a manner that defines an orifice therebetween. Because the Camilli reference does not disclose each of the elements included in any of claims 36-41, it cannot represent anticipatory prior art under 35 USC §102. Withdrawal of this rejection is thus requested.

Examiner's Point No. 11:

Claims 1 and 36 (the independent claims of the rejected group) are being amended to add 'a support frame configured for expansion to conform to a wall of the bodily passage' to which the covering or leaflets is/are attached. Cox discusses use of 'reinforcing strips', or an 'angioplasty ring' as an optional support mechanism, but does not disclose an expandable support frame as claimed. Withdrawal of this rejection is thus requested.

Examiner's Point No. 12:

Claim 1 is being amended whereby the outer edge is 'at least partially attached' along the sides of the frame in a path 'extending at least partially longitudinally along the wall and at least partially circumferentially around the wall', something clearly not disclosed by Bessler. Claim 19 requires a leaflet having "a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by one of the plurality of legs, the outer edge and the associated let adapted to sealingly engage the inner wall of the bodily passage" and further has been amended to include the limitation whereby the device is 'adapted to trap between the leaflets and the inner wall of the bodily passage fluid' which closes the leaflets and restricts retrograde fluid flow. Bessler does not teach these features. Bessler teaches attachment of the top of the cuff (see item #26 in Bessler) to the stent at a few spaced locations, and does not teach trapping fluid between the leaflet and the wall as claimed – the Bessler leaflets extend

transversely across the internal portion of the frame. Claim 36 is amended in a manner similar to Claim 19. Bessler does not trapping fluid between the leafetthe arcuate outer edge of the leaflets sealing against the vessel wall, nor does it disclose the trapping of fluid between the leaflet and vessel wall to close the valve. With regard to amended claim 46, Bessler does not teach attachment of the covering to the support frame along the specified path. Therefore claims 1, 19, 36, and 46 are allowable as well as those claims that depend therefrom. Withdrawal of this rejection is thus requested.

Claim Rejections - 35 USC §103

Examiner's Point No. 14:

Because of the amendments made to overcome rejections under 35 USC 102, the combination of Bessler and Cox clearly lack the teachings to make a case of obviousness under 35 § 103. In particular, Bessler does not teach attachment of the outer edge of the covering to the frame in the manner prescribed by the claims, nor does Bessler teach the trapping of the fluid between the leaflets and the walls of the vessel.

The Examiner has indicated that claims 6,13, and 30 would be allowable if rewritten to overcome rejections(s) under 35 U.S.C. 112, second paragraph. Applicants feel that they have made the necessary amendments and/or arguments for allowance of the claims from which these claims depend.

New claims 50-55 have been added. It is believed that these claims are also patentable over the prior art. Favorable consideration is therefore solicited.

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner, if so necessary, to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment..

Respectfully submitted,

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Enclosure:
Petition for 2-month Extension of Time

MARKED-UP CLAIMS

1. An implantable valve for a bodily passage of tubular shape, comprising:

a support frame configured for expansion to conform to a wall of the bodily passage, said support frame when expanded providing a plurality of side elements each defining a path extending at least partially longitudinally along the wall and at elast partially circumferentially around the wall,

a plurality of leaflets, each leaflet thereof having a body extending from a wall-engaging outer edge to an inner edge proximate a corresponding inner edge of at least one [or another] other leaflet of the plurality of leaflets,

the inner edges of said plurality of leaflets cooperable to define an opening therebetween to permit fluid flow in a first direction along the bodily passage, and further cooperable to engage each other sufficiently to restrict [at least substantially occlude] fluid flow in a second direction opposing the first direction,

the outer edge of each one of the plurality of leaflets attached along one side element of said plurality of side elements and thereby adapted to engage [a] the wall of the bodily passage in said path extending [oriented] at least partially longitudinally [therealong] and at least partially circumferentially [therearound] such that the leaflet extends along said bodily passage away from the inner edges in said second direction[,].

5. The implantable valve of claim 3 wherein said frame comprises [a] wire to and around which the bodies of the leaflets are secured.

6. The implantable valve of claim 1 wherein the [covering] plurality of leaflets includes two leaflets such that when the frame is substantially

flattened, it assumes a diamond shape with the inner edges of the two leaflets defining a slit therebetween.

10. The implantable valve of claim 1 wherein the [covering] plurality of leaflets comprise[s] an extracellular collagen matrix.

19. An implantable valve for a bodily passage of tubular shape, comprising:

a frame that includes a plurality of legs, each of the legs originating from a pair of bends located about a first end of the implantable valve, and extending in an opposite direction therefrom, each of the plurality of legs terminating at the second end of the implantable valve such that the plurality of legs generally assume a serpentine configuration along the circumference of a bodily passage when situated therein,

a plurality of leaflets, each leaflet comprising a covering that includes one or more flexible materials, the leaflet including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by one of the plurality of legs, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily passage,

wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge traversing the lumen of the bodily passage when situated therein and being configured such that the leaflet is cooperable with at least one other leaflet to define an opening that permits positive flow of fluid therethrough in a first direction, while the plurality of leaflets are further adapted to trap between the leaflets and the inner wall of the bodily passage fluid flowing in a second direction opposite the first direction

and seal against one another to [at least substantially reduce retrograde] restrict fluid flow in said second direction.

[27.] 48. The implantable valve of claim 19 wherein the frame is formed into the serpentine configuration.

[28.] 49. The implantable valve of Claim 19 wherein the frame comprises a bioabsorbable material.

46. An implantable valve for a bodily passage of tubular shape, comprising:

a self-expanding frame that includes a pair of legs, each of the legs originating from a pair of bends located about a first end of the implantable valve, and extending in a opposite direction therefrom, each of the pair of legs terminating about the second end of the implantable valve such that the pair of legs generally and collectively assume a serpentine configuration along the circumference of a bodily passage when situated therein;

a plurality of barbs, at least one barb attached to each of the pair of legs, at least one of the barb including a terminal projection, the terminal projection configured to releasably engage with a delivery system for deployment of the inplantable valve into the bodily passage;

a pair of leaflets, each leaflet comprising tissue derived from an extracellular collagen matrix, each of the leaflets including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by the frame, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily passage,

wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge

traversing the lumen of the bodily passage when situated therein and being configured such that the leaflet is cooperable with the other of the plurality of leaflets to define an opening that permits positive flow of fluid therethrough, while the pair of leaflets are further adapted to trap fluid between the leaflets and the inner wall of the vessel and seal against one another to [at least substantially reduce] restrict retrograde flow.

47. An implantable valve for a bodily passage of tubular shape, comprising:

a self-expanding frame that includes a pair of legs, each of the legs originating from a pair of bends located about a first end of the implantable valve, and extending in a opposite direction therefrom, each of the pair of legs terminating about the second end of the implantable valve such that the pair of legs generally and collectively assume a serpentine configuration along the circumference of a bodily passage when situated therein;

a plurality of barbs, at least one barb attached to each of the pair of legs, at least one of the barb including a terminal projection, the terminal projection configured to releasably engage with a delivery system for deployment of the inplantable valve into the bodily passage;

a pair of leaflets, each leaflet comprising tissue derived from an extracellular collagen matrix, each of the leaflets including a body that comprises a wall-engaging outer edge and an inner edge, the outer edge at least partially attached to, and reinforced by the frame, the outer edge and the associated leg adapted to sealingly engage the inner wall of the bodily passage,

wherein the body of the leaflet extends inward from the wall of the bodily passage and extending toward the first end of the implantable valve where it terminates at the inner edge, the body and inner edge traversing the lumen of the bodily passage when situated therein and

being configured such that the leaflet is cooperable with the other of the plurality of leaflets to define an opening that permits positive flow of fluid therethrough, while the pair of leaflets are further adapted to trap fluid between the leaflets and the inner wall of the vessel and seal against one another to [at least substantially reduce] restrict retrograde flow.